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Proposed Registration Decision

Pantoea agglomerans strain C9-1

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

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Overview

Proposed Registration Decision for *Pantoea agglomerans* strain C9-1

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing conversion from conditional to full registration for the sale and use of *Pantoea agglomerans* strain C9-1 Technical and BlightBan C9-1, containing the microbial pest control agent (MPCA) *Pantoea agglomerans* strain C9-1 Technical, for the suppression of fire blight (*Erwinia amylovora*) on apple and pear trees, saskatoonberries, caneberries and non-bearing pome fruit nursery stock.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of *Pantoea agglomerans* strain C9-1 Technical and BlightBan C9-1.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2], when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on *Pantoea agglomerans* strain C9-1 Technical, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on *Pantoea agglomerans* strain C9-1 Technical, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is *Pantoea agglomerans* strain C9-1 Technical?

Pantoea agglomerans is ubiquitous in nature and occurs naturally on fruit trees. As the active ingredient in BlightBan C9-1, it colonizes flowers and other parts of fruit trees and occupies sites that would otherwise be colonized by the fireblight pathogen, *Erwinia amylovora*. BlightBan C9-1 will suppress fireblight on fruit trees and shrubs when applied during flowering.

Health Considerations

Can Approved Uses of *Pantoea agglomerans* strain C9-1 Technical Affect Human Health?

Pantoea agglomerans strain C9-1 Technical is unlikely to affect your heath when BlightBan C9-1 is used according to the label directions.

Exposure to *Pantoea agglomerans* strain C9-1 Technical may occur during handling and application of BlightBan C9-1. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (e.g. production of toxic by-products);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the levels to which people may be exposed, relative to exposures already encountered in nature to other isolates of the microorganism.

Toxicology studies in laboratory animals describe potential health effects from large doses in an effort to identify any potential to cause disease or toxicity. When *Pantoea agglomerans* strain C9-1 Technical was tested on laboratory animals there were no signs that it caused any significant toxicity or disease.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Other strains of *P. agglomerans* found in nature have been associated with minor wound infections involving punctured skin; however, there is no indication that infection would arise if healthy skin is penetrated. This species of microorganisms does not cause disease in humans and is not known to produce byproducts that are harmful to humans or other animals.

Pantoea agglomerans strains of bacteria contain a substance in their cell walls called lipopolysaccharide that can shed from the cells as tiny "pockets". If inhaled in large amounts, the lipopolysaccharide can cause inflammation in the respiratory system. Upon repeated exposure to this product, people, such as farm workers and applicators, could develop a condition know as respiratory hypersensitivity. Like all bacteria, *Pantoea agglomerans* strain C9-1 Technical contains other substances that can cause allergic reactions in people who are repeatedly exposed to it at high concentrations. However, these reactions can be avoided if farm workers and applicators follow label recommendations to minimize exposure to BlightBan C9-1, including wearing a dust mask.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Strains of *P. agglomerans* are common in nature, and the use of BlightBan C9-1 in orchards to suppress fireblight on apple and pear trees is not expected to significantly increase the natural environmental background levels of this microorganism. Furthermore, when *Pantoea agglomerans* strain C9-1 Technical was administered orally to rats, no signs of toxicity or diseases were observed. Other than the cell wall lipopolysaccharide, that can cause inflammation in the respiratory system upon repeated exposure, strains of *P. agglomerans* are not known to produce toxicologically significant secondary metabolites. Consequently, the risks from secondary metabolites for the general population, including infants and children or animals, are negligible. Therefore, the establishment of a MRL is not required for *Pantoea agglomerans* strain C9-1 Technical. As well, the likelihood of residues of *Pantoea agglomerans* strain C9-1 Technical contaminating drinking water supplies is negligible to non-existent. Consequently, dietary exposure and risk are minimal to non-existent.

Occupational Risks From Handling BlightBan C9-1

Occupational risks are not of concern when BlightBan C9-1 is used according to label directions, which include protective measures.

Growers handling BlightBan C9-1 can come into direct contact with *Pantoea agglomerans* strain C9-1 Technical on the skin, in the eyes or by inhalation. For this reason, the label specifies that growers exposed to BlightBan C9-1, during handling, mixing/loading, application or clean-up/repair activities, must wear waterproof gloves, long-sleeved shirts, long pants, shoes plus socks, and a National Institute of Occupational Safety and Health (NIOSH) approved respirator with any N-95, R-95, P-95 or HE filter. Furthermore, early entry workers are restricted from entering areas where BlightBan C9-1 has been applied as a foliar spray for a period of four hours unless wearing the above mentioned personal protective equipment (PPE).

Bystander exposure is expected to be much less than that of applicators, handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Pantoea agglomerans* strain C9-1 Technical Is Introduced Into the Environment?

Studies designed to examine the effects of *Pantoea agglomerans* strain C9-1 Technical on various non-target organisms were evaluated. Few adverse effects were observed in birds, terrestrial arthropods (honeybees), freshwater fish and freshwater arthropods.

Pantoea agglomerans strain C9-1 Technical is not generally considered a disease-causing agent. Therefore, BlightBan C9-1 is expected to present negligible risk to non-target organisms.

Value Considerations

What Is the Value of BlightBan C9-1?

BlightBan C9-1 is registered to suppress fireblight on apples, pears, saskatoonberries, caneberries and non-bearing pome fruit nursery stock.

BlightBan C9-1 is an alternative product to Streptomycin 17, a bactericide currently registered for fireblight control. Suppression of the fireblight pathogen (*Erwinia amylovora*) with BlightBan C9-1 will reduce grower reliance on streptomycin.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of BlightBan C9-1 to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

As there are concerns with users developing allergic reactions through repeated high exposures to *Pantoea agglomerans* strain C9-1 Technical, anyone handling, mixing/loading, applying or involved in clean-up/repair activities of BlightBan C9-1 must wear waterproof gloves, long-sleeved shirts, long pants, shoes plus socks and a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter. Furthermore, early entry workers are restricted from entering areas where BlightBan C9-1 has been applied as a foliar spray for a period of four hours unless wearing the above indicated PPE.

Environment

As a general precaution, handlers are asked not to contaminate irrigation or drinking water or aquatic habitats through equipment cleaning or waste disposal. In addition, growers must not allow effluent or runoff containing this product to enter lakes, streams, ponds or other water bodies.

Precautionary labelling indicating that handlers must avoid application of BlightBan C9-1 on orchards abutting newly planted conifer forestry blocks will mitigate the risk of gall formation by the MPCA in potentially susceptible seedlings.

Next Steps

Before making a final registration decision on *Pantoea agglomerans* strain C9-1 Technical, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document.

Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on *Pantoea agglomerans* strain C9-1 Technical (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Pantoea agglomerans strain C9-1 Technical

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active microorganism	***Pantoea agglomerans* strain C9-1**
Function	Suppression of fire blight (*Erwinia amylovora*) on apple and pear trees, saskatoonberries, caneberries and non-bearing pome fruit nursery stock
Binomial name	*Pantoea agglomerans* strain C9-1
Taxonomic designation	
Kingdom	Eubacteria
Phylum	Proteobacteria
Class	Gammaproteobacteria
Order	Enterobacteriales
Family	Enterobacteriaceae
Genus	*Pantoea*
Species	*agglomerans*
Strain	C9-1
Patent status information	None
Nominal purity of active ingredient	7.5×10^{11} colony forming unit (CFU)/g
Identity of relevant impurities of toxicological, environmental and/or other significance	The technical grade active ingredient does not contain any impurities or microcontaminants known to be Toxic Substances Management Policy (TSMP) Track 1 substances. The product must meet microbiological contaminants release standards and, except for lipopolysaccharide (a component of all Gram-negative bacteria), no mammalian toxins are known to be produced by *Pantoea agglomerans* strain C9-1.

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—*Pantoea agglomerans* strain C9-1 Technical

Property	Result
Colour	White
Odour	Odourless
Physical state	Powder
Specific gravity	0.4 g/mL
pH (in solution)	6.7 (as a suspension)

End-Use Product—BlightBan C9-1

Property	Result
Colour	White
Odour	Odourless
Physical state	Powder
Formulation type	LO (live organism)
Guarantee	1×10^{11} CFU/g
Formulants	The product does not contain any United States Environmental Protection Agency List 1 formulants or formulants known to be TSMP Track 1 substances.
Container material and description	Foil lined, laminate covered, sealed pouches
Storage stability	Storage stability data supports a shelf-life of 15 months when stored at temperatures below -20°C.

1.3 Directions for Use

Please refer to REG2006-13, Section 7.1.1, for more information on the **DIRECTIONS FOR USE** of BlightBan C9-1.

1.4 Mode of Action

Please refer to REG2006-13, Section 7.1.2, for more information on the mode of action of BlightBan C9-1.

2.0 Methods of Analysis

2.1 Methods for Identification of the Microorganism

The MPCA is identified to the species level by gas chromatography of fatty acid methyl esters (GC-FAME) and by comparison of Biolog biochemical profiles with a library of species' profiles. Identitification of the MPCA was also confirmed using 16S rDNA sequence analysis.

Strain specific identification of *P. agglomerans* strain C9-1 is achieved by its resistance to antibiotics rifampicin and streptomycin, and by polymerase chain reaction analyses using repetitive DNA sequences ("BOX elements") and enterobacterial repetitive intergenic consensus primers.

2.2 Methods for Establishment of Purity of Seed Stock

From the time of its original isolation from "Jonathan" apple stem tissue in Michigan, *P. agglomerans* strain C9-1 was maintained at ultralow temperatures in appropriate media.

The master stock was grown in standard broth from which sixty cryogenic vials samples are stored in liquid nitrogen. The cryogenic samples are checked for purity every 12 months. The identity of the MPCA in the master stock was also confirmed as *P. agglomerans* strain C9-1 using the API 20 identification system. The master stock has never been replenished.

2.3 Methods to Define the Content of the Microorganism in the Manufactured Material Used for the Production of Formulated Products

Composite samples from each production lot are tested using colony counts on standard and antibiotic-amended media to determine the number of colony forming units of *P. agglomerans* strain C9-1 per unit mass of sample (CFU/g). The nominal guarantee for BlightBan C9-1 is based on total cell counts, rather than antibiotic-resistant cell counts.

2.4 Determination and Quantification Residues (viable or non-viable) of the Active Microorganism and Relevant Metabolites

Although *P. agglomerans* is ubiquitous in nature and has been isolated from a wide variety of environments, no adverse effects from dietary exposure have been attributed to natural populations of *P. agglomerans*. The value of the acute oral toxicity and infectivity/pathogenicity study was compromised by the possible loss of test substance viability in the acid environment of the stomach. However, in the acute intravenous pathogenicity study in which innate host barriers to infection are bypassed, the test substance could not be recovered from the host after three days. This indicates that the MPCA is not infective or even viable in rats. Adverse effects attributable to bacterial lipopolysaccharide are not expected on oral exposure, and there are no reports of other mammalian toxins being produced by the MPCA. Furthermore, the pesticide is not expected to come into direct contact with the fruit because of the timing of its application (during bloom). The establishment of a MRL is therefore not required for *P. agglomerans* strain C9-1 under section 4(d) of the *Food and Drugs Act* (adulteration of food) as defined under Division 15, section B.15.002 of the Food and Drug Regulations.

2.5 Methods for Determination of Relevant Impurities in the Manufactured Material

Microbial contamination during the manufacturing of BlightBan C9-1 is minimized by sterilizing the starting and intermediate materials as well as the equipment used during fermentation, harvest and product formulation. Other factors that may minimize the contamination of the fermentation product or end-use product with human pathogens include the incubation temperature and the growth medium, both of which are not conducive to the growth of many human pathogens. The maximum acceptable level of contamination is 1×10^3 CFU/mL.

2.6 Methods to Show Absence of Any Human and Mammalian Pathogens

As noted in Section 2.5, several approaches are used to limit microbial contamination in *Pantoea agglomerans* strain C9-1 Technical and BlightBan C9-1. Further contaminant testing using standard plating methods with appropriate enrichment steps is also performed on composite samples from each production lot to distinguish human and mammalian pathogens such as *Salmonella*, *Shigella*, *Staphylococcus* sp., enterics, *Vibrio* sp., yeasts and moulds as well as *Pseudomonas aeruginosa* and enteric bacteria. Representative quality assurance data support these claims.

2.7 Methods to Determine Storage Stability, Shelf-Life of the Microorganism

Storage stability data were sufficient to support a shelf-life of 15 months for BlightBan C9-1, when the product is stored at temperatures below -20°C.

3.0 Impact on Human and Animal Health

Please refer to REG2006-13, for a detailed summary of the toxicology review, the occupational exposure assessment and the food residue exposure assessment.

4.0 Impact on the Environment

Please refer to REG2006-13 for details of the environmental fate and environmental toxicology assessment.

5.0 Value

5.1 Effectiveness Against Pests

For information on the effectiveness of BlightBan C9-1 against fireblight on pears and apples, refer to REG2006-13, Section 7.1.3.

5.1.1 Acceptable Efficacy Claims

Information on acceptable efficacy claims for apple and pear can be found in REG2006-13, Section 7.1.3. In addition to suppressing fireblight on apples and pears, BlightBan C9-1 is also registered for the suppression of this disease on saskatoonberries, caneberries and non-bearing pome fruit nursery stock at the same rates. Applications should be made at 15–20% bloom,

followed by a second application at full bloom and a third immediately at postbloom. The higher rate should be applied under conditions of high disease pressure.

5.2 Sustainability

5.2.1 Survey of Alternatives

Active ingredients registered for fireblight control on apples and pears include streptomycin and fixed copper in the form of copper oxychloride. Copper products are registered on pears in British Columbia only. The product Apogee (prohexadione calcium) is also registered as a plant growth regulator on apple trees to reduce vegetative growth. Controlling vegetative growth will suppress fireblight infection by decreasing host susceptibility. The addition of BlightBan C9-1 as a tool to suppress fireblight will provide growers with another means to protect their fruit crops and minimize losses. It will reduce the reliance of growers on streptomycin, which will help delay the development of resistance in *E. amylovora* and decrease occupational exposure to this bactericide.

5.2.2 Compatibility with Current Management Practices Including Integrated Pest Management

For information on compatibility of BlightBan C9-1 with current management practices, including integrated pest management, refer to REG2006-13, Section 7.4.

5.2.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

For information on the occurrence or possible occurrence of development of resistance, refer to REG2006-13, Section 7.2.

5.2.4 Contribution to Risk Reduction and Sustainability

For information on risk reduction and sustainability, refer to REG2006-13, Section 7.4.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's TSMP, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

In its review, the PMRA took into account the federal TSMP and followed its Regulatory Directive DIR99-03, *The PMRA's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with its use were also considered, including microcontaminants in the technical product, *Pantoea agglomerans* strain C9-1 Technical, and formulants in the end-use product, BlightBan C9-1. The PMRA has reached the following conclusions.

Pantoea agglomerans strain C9-1 does not meet the Track 1 criteria because the active ingredient is a biological organism; hence, it is not subject to the criteria used to define persistence, bioaccumulation and toxicity properties of chemical control products. There are also no formulants, contaminants or impurities present in the end-use product that would meet the TSMP Track 1 criteria.

Therefore, the use of *Pantoea agglomerans* strain C9-1 Technical and BlightBan C9-1 is not expected to result in the entry of Track 1 substances into the environment.

6.2 Formulants and Contaminants of Health or Environmental Concern

Pantoea agglomerans strain C9-1 Technical, and the end-use product, BlightBan C9-1, do not contain any contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.

7.0 Summary

7.1 Methods for Analysis of the Microorganisms as Manufactured

The product characterization data for *P. agglomerans* strain C9-1 and BlightBan C9-1 were judged to be adequate to assess their potential human health and environmental risks. The technical material was fully characterized and the specifications were supported by the analyses of a sufficient number of batches. The effectiveness of the quality assurance program in limiting contaminating microorganisms is supported by representative quality assurance data.

Storage stability data were sufficient to support a shelf-life of 15 months for BlightBan C9-1 when the product is stored at temperatures below -20°C.

7.2 Value

The claim for suppression of fireblight on apples, pear, saskatoonberry, caneberries and non-bearing pome fruit nursery stock is acceptable based on the submitted scientific data.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of *Pantoea agglomerans* strain C9-1 Technical and BlightBan C9-1, containing the technical grade active ingredient, *Pantoea agglomerans* strain C9-1 Technical to suppression of fireblight (*Erwinia amylovora*) on apple and pear trees, saskatoonberries, caneberries and non-bearing pome fruit nursery stock.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

CFU	colony forming units
g	gram
GC-FAME	gas chromatography of fatty acid methyl esters
mg	milligram
mL	millilitre
MPCA	microbial pest control agent
MRL	maximum residue limit
N/A	not applicable
NIOSH	National Institute for Occupational Safety and Health
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
TSMP	Toxic Substances Management Policy

Appendix I Tables and Figures

Table 1 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Applicant-proposed Label Claims	Accepted Label Claims	Unsupported Label Claims and Comments
Suppression of fireblight (*Erwinia amylovora*) on apples, pears, saskatoonberry, caneberries and non-bearing pome fruit nursery stock	Suppression of fireblight (*Erwinia amylovora*) on apples, pears, saskatoonberry, caneberries, and non-bearing pome fruit nursery stock	N/A

References

A. List of Studies/Information Submitted by Registrant

Chemistry

PMRA Number	Title
PMRA 1460063	2007, *Pantoea agglomerans* Strain C9-1: A Strain Specific Method of Identification, PAG-VS-150107, DACO: M2.7.1 CBI
PMRA 1460083	2007, Certificate of Analysis: *Pantoea agglomerans* C9-1, PAG-Osprey-180407, DACO: M2.10 CBI
PMRA 1617899	2008, Assessment of Viability, 08Ea297, DACO: 2.14.14 CBI
PMRA 1625789	2008, Clarification Response 01 August 2008, DACO: 0.8.23
PMRA 1625790	2008, Pseudomonas Plate Count Procedure, DACO: 3.4 CBI

B. Additional Information Considered

Value

PMRA Number	Title
PMRA 1563403	2008, Submission No. 2008-0898: Evaluation Report for Category C, Subcategory 6.3 (URMULE) Application